Questions and Answers about Hib Vaccine Recall

1. What vaccine is being recalled?

Merck & Co. has initiated a voluntary recall in the United States for ten lots of PedvaxHIB® [Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)] and two lots of COMVAX® [Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine]. The affected doses were distributed in the U.S. starting in April 2007.

2. Why are these lots being recalled?

Merck is taking this step as a precautionary measure. The company cannot assure sterility for these specific vaccine lots. The potential contamination in these specific lots was identified as part of Merck's standard evaluation of their manufacturing processes. In routine testing of the vaccine manufacturing equipment used to produce PedvaxHIB® and COMVAX®, Merck identified the presence of a certain bacteria called Bacillus cereus. Sterility tests of the vaccine lots themselves have not found any contamination.
The potential for contamination of any individual vaccine is low, and, if present, the level of contamination would be low. However, because they cannot guarantee the sterility of these specific lots of vaccine, Merck is conducting this recall.

3. What is the extent of the recall?

About 1 million doses of vaccine are being recalled, including ten lots of PedvaxHIB® and two lots of COMVAX® that were distributed in the U.S. as well as vaccine lots within the CDC stockpile.

4. Will children who received vaccine from affected lots need to be revaccinated?

No. Children who received Hib vaccine from affected lots do not need to be revaccinated. No potency concerns have been identified for these vaccine lots.

5. What are the risks to children who received vaccine from affected lots?

Sterility tests of the vaccine lots themselves have not found any contamination. Merck has not received any reports of abscesses or disseminated B. cereus infection in children who received vaccines from affected lots. In addition, no problems have been detected by the Vaccine Adverse Event Reporting System (VAERS) related to the Hib vaccine affected by this recall. However, since sterility of the vaccine cannot be assured, if a child was vaccinated with a vial of PedvaxHIB® or COMVAX® that contained B. cereus or other microorganisms, there may be a risk of developing localized or disseminated infections. Immunocompromised children may be at the greater risk for these infections. These infections are most likely to occur within one week after vaccination.

(Source: Centers for Disease Control and Prevention (CDC), December 12, 2007)